APR 2 8 2014

K133271

510(k) Summary

510(k) Owner:	Owandy Le Coruscant, 2 rue des Vieilles Vignes 77183 Croissy-Beaubourg France
Contact Person:	Olivier Maurier Phone: 0033-164-111818
Date Prepared:	October 21, 2013
Consultant:	Denterprise International, Inc. 110 E. Granada Blvd., Suite 207 Ormond Beach, FL 32176 386-672-0450 (Voice) 386-672-4402 (Fax)
Primary Contact: *Secondary Contact:*	Claude Berthoin, President (claude@510kfda.com) John Gillespy, VP Regulatory Affairs (john@510kfda) Holly Layne, Assistant (holly@510kfda)
Trade Name: *Device Models:*	Opteo Opteo T1, Opteo T2, Videograph HD #1, Videograph HD #2 (Videograph HD is an OEM version of Opteo)
Common Name:	Intraoral Digital X-Ray Sensor
Classification Name:	Extraoral Source X-Ray System (Component); 21 CFR 872.1800; Product Code MUH
Predicate Device:	Visteo (Owandy) K093105
Device Description:	Intraoral detector for capturing x-ray images from an extraoral source generator. Captured images are automatically transmitted in digital form via USB connection for display, storage, and printing on the practitioner's computer using imaging software.

Indications For Use: The OPTEO digital system is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose, by dental practitioners. This is achieved by using the conventional x-ray tube, and placing an electronic sensor in the patient's mouth instead of conventional film. The sensor, upon radiation exposure, automatically captures the images into a computer. The computer, which is not provided by OWNDY, controls all aspects of

image acquisition and image display, storage and printing. Additional software (after, and not part of, image capture software) is available on the market. They allow for enhancements such as zoom, contrasts controls, image inversion, and pseudo color renditions.

The main advantages of this digital imaging system are:

- high definition ensuring high-value diagnostics
- interface allowing image processing in the PC

In no case, it has to be used directly by the patient. So, it is used exclusively in a healthcare specific environment.

Technological Characteristics: The device is a modified version of the predicate and is similar in terms of basic component materials, overall design, and labeling... Both the original predicate and the 510(k) device are covered with a single-use disposable hygienic sheath and positioned in the patient's mouth for radiographic examination of areas of the oral region. An external x-ray generator emits radiation that is partially absorbed by bone areas and soft tissue. Unabsorbed x-rays strike a scintillator in the device which converts the x-ray energy beam into light. An optical fiber filters this stream of photons. The light then hits an electron light sensor (CMOS) that in turn reemits it in the form of an electrical pulse. The resulting pixel matrix is sent to a connected computer and saved as a gray-scale image. Imaging software on the PC processes the image and enables nearly instant viewing and storage of the x-ray image... A comparison of the subject and predicate, which shows the devices have the same performance characteristics and equivalent safety and efficacy profiles, is provided in Section 12.

Device Modifications... The only significant modification to the original Visteo was integration of control box electronics with sensor board electronics in order to eliminate the control box, as more fully discussed in Section 12. A risk analysis and electrical and EMC testing were performed on the device, as discussed below.

Safety Assessment: Device material safety and design have been established in 510(k) submission K093105 (Visteo). Biocompatibility testing is not warranted since both the subject and predicate devices are covered with disposable sheaths during use.

Risk Analysis: A risk analysis assessment of the impact of modifications on the device and its components was performed in conformance with ISO 14971:2009. Results of that analysis determined the residual risks inherent in the use of the Opteo are "acceptable."

EMC and Electrical Safety Testing: IEC 60601-1 and 6-0601-1-2 testing was performed to demonstrate continued conformance with recognized standards.

Conclusions: Both intended use and fundamental scientific technology are the same in both the subject and predicate devices. A comparison of technological features, a risk analysis of modifications, and electromagnetic compatibility and electrical safety tests support the conclusions that the subject Opteo is safe for its intended use and is substantially equivalent to the predicate Visteo.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

OWANDY
% Mr. Claude Berthoin
President
Denterprise International, Inc.
110 East Granada Blvd., Suite 207
ORMOND BEACH FL 32176

Re: K133271
Trade/Device Name: Opteo, Videograph HD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March31, 2014
Received: April 3, 2014

Dear Mr. Berthoin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

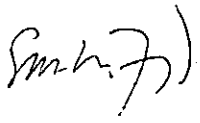
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133271

Device Name
Opteo Intraoral X-Ray Sensor

Indications for Use *(Describe)*

The Opteo digital system is designed to collect instant images of human oral tissue and teeth without the use of a conventional x-ray film. It is used with a conventional x-ray tube and a computer for dental radiographic imaging. The Opteo is covered with a single use disposable sheath and positioned in the oral cavity opposite the tooth the dentist wishes to x-ray. The dental x-ray tube (which is not part of Opteo) is pointed at the sensor and activated. The emitted radiation from the x-ray tube is detected by the sensor and transmitted as a data stream to the computer system that the device is connected to.

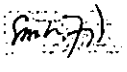
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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